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**INFORMATION DISCLOSURE
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Application Number

09/723,713

Filing Date

November 27, 2000

First Named Inventor

Schenk, Dale B.

Group Art Unit

1647

Examiner Name

Turner, Sharon

Attorney Docket Number

15270J-004741US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	267	6,294,171	B2	McMichael	09-25-2001	
	234	6,284,221	B1	Schenk, et al.	09-04-2001	
	300	2001/0018053	A1	McMichael	08-30-2001	
	230	6,262,335	B1	Hsiao et al.	07-17-2001	
	231	6,114,133		Seubert et al.	09-05-2000	
	221	5,989,566		Cobb et al.	11-23-1999	
	284	5,231,170		Averback	07-27-1993	
	242	60/168,594		Chalifour et al.	N/A	
	282	60/169,687		Chain	N/A	
	295	60/184,801		Holtzman et al.	N/A	
	299	60/186,295		Rasmussen et al.	N/A	
	296	60/254,465		Holtzman et al.	N/A	
	297	60/254,498		Holtzman et al.	N/A	
	283	09/441,140		Solomon et al.	N/A	

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	243	PCT	01/39796	A2		06-07-2001		
	298	PCT	01/42306	A2		06-14-2001		
	301	PCT	01/62284	A2		03-01-2000		
	294	PCT	01/62801	A2		08-30-2001		
	240	PCT	00/43039	A1		07-27-2000		
	227	PCT	95/11008	A2		04-27-1995		

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Substitute for form 1449B/PTO <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(use as many sheets as necessary)</p>		<h3 style="text-align: center;">Complete if Known</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Applicant Number</td> <td>09/723,713</td> </tr> <tr> <td>Filing Date</td> <td>November 27, 2000</td> </tr> <tr> <td>First Named Inventor</td> <td>Schenk, Dale B.</td> </tr> <tr> <td>Group Art Unit</td> <td>1647</td> </tr> <tr> <td>Examiner Name</td> <td>Turner, Sharon</td> </tr> <tr> <td>Attorney Docket Number</td> <td>15270J-004741US</td> </tr> </table>		Applicant Number	09/723,713	Filing Date	November 27, 2000	First Named Inventor	Schenk, Dale B.	Group Art Unit	1647	Examiner Name	Turner, Sharon	Attorney Docket Number	15270J-004741US
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Sheet	2	of	6												

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
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25	228	BARROW, et al., "Solution Conformations and aggregational Properties of Synthetic Amyloid Beta-Peptides of Alzheimer's Disease. Analysis of Circular Dichroism Spectra" <u>J. Mol. Biol.</u> , 225(4): 1075-1093 (1992).	✓
	239	BEASLEY, "Alzheimer's traced to proteins caused by aging." Reuters, April 20, 2001 7:56 PM ET.	✓
	285	CAPUTO et al., "Therapeutic approaches targeted at the amyloid proteins in Alzheimer's disease," <u>Clin. Neuropharm.</u> , 15:414A-414B (1992).	✓
	224	Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Thimerosal in Vaccines (Mercury in Plasma-Derived Products), web site contents found at : http://www.fda.gov/cber/vaccine/thimerosal.htm , last updated May 16, 2002.	✓
25	266	CHAPMAN, PAUL F., "Model behavior," <u>Nature</u> , 408:915-916 (2000).	✓
	222	Chemical Abstract database, Abstract of "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals," Chemical Abstract database. (Publication date unknown:) <i>improper format</i>	✓
	302	CHUNG et al. "Uptake, Degradation, and Release of Fibrillar and Soluble Forms of Alzheimer's Amyloid β -Peptide by Microglial Cells," <u>J. Biol. Chem.</u> , 274(45):32301-32308 (1999).	✓
	291	COLOMA et al., "Transport Across the Primate Blood-Brain Barrier of a Genetically Engineered Chimeric Monoclonal Antibody to the Human Insulin Receptor," <u>Pharm. Res.</u> , 17:266-274 (2000).	✓
25	286	CORDELL, B., " β -Amyloid formation as a potential therapeutic target for Alzheimer's disease," <u>Ann. Rev. Pharmacol. Toxicol.</u> , 34:69-89 (1994).	✓
	287	COSTA et al., "Immunoassay for transthyretin variants associated with amyloid neuropathy," <u>Scand. J. Immunol.</u> , 38:177-182 (1993).	✓
	293	DALY, et al., "Detection of the membrane-retained carboxy-terminal tail containing polypeptides of the amyloid precursor protein in tissue from Alzheimer's Disease brain," <u>Life Sci.</u> , 63:2121-2131 (1998).	✓
	220	Dialog/Derwent, Abstract of WPI Acc. No.: 1997-054436/199706: Stable vaccine compsns. -- comprise a macrocyclic lactone, a milbemycin, an avermectin, an antigen, a dispersing agent, an adjuvant, a water-sol. organic solvent and saline or water; Derwent File 351: Derwent-WPI database. (Publication date unknown:) <i>improper format</i>	✓
25	288	DUMERY et al., " β -Amyloid protein aggregation: its implication in the physiopathology of Alzheimer's disease," <u>Pathol. Biol.</u> , 49:72-85 (2001).	✓
	225	Elan, "Elan and AHP Provide an Update on the Phase 2A Clinical Trial of AN-1792," Press Release. (1/28/2002).	✓

Examiner Signature		Date Considered	11-28-02
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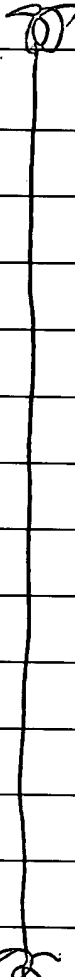
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Sheet 3 of 6

Complete if Known

Application Number	09/723,713
Filing Date	November 27, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1647
Examiner Name	Turner, Sharon
Attorney Docket Number	15270J-004741US

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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	226	Elan, "Elan and Wyeth Provide Update on Status of Alzheimer's Collaboration," Press Release (3/1/2002).	
	289	ESIRI, "Is an effective immune intervention for Alzheimer's disease in prospect?," <u>Trends in Pharm. Sci.</u> , 22:2-3 (2001).	
	246	FRENKEL et al., "Generation of auto-antibodies towards Alzheimer's disease vaccination," <u>Vaccine</u> , 19:2615-2619 (2001).	
	247	FRENKEL et al., "Immunization against Alzheimer's β -amyloid plaques via EFRH phage administration," <u>PNAS USA</u> , 97:11455-11459 (2000).	
	248	FRENKEL et al., "N-terminal EFRH sequence of Alzheimer's β -amyloid peptide represents the epitope of its anti-aggregating antibodies," <u>J. of Neuroimmunology</u> , 88:85-90 (1998).	
	245	FRENKEL et al., "High affinity binding of monoclonal antibodies to the sequential epitope EFRH of β -amyloid peptide is essential for modulation of fibrillar aggregation," <u>J. of Neuroimmunology</u> , 95:136-142 (1999).	
	244	FRENKEL, et al., "Modulation of Alzheimer's β -amyloid neurotoxicity by site-directed single chain antibody," <u>J. of Neuroimmunology</u> , 106:23-31 (2000).	
	249	FRIEDLAND, et al., "Neuroimaging of Vessel Amyloid in Alzheimer's Disease," in <u>Cerebrovascular Pathology in Alzheimer's Disease</u> , eds. de la Torre and Hachinski, New York Academy of Sciences, New York, New York (1997).	
	251	GARDAELLA et al., "Intact Alzheimer amyloid precursor protein (APP) is present in platelet membranes and is encoded by platelet mRNA," <u>Biochem. Biophys. Res. Comm.</u> , 173:1292-1298 (1990).	
	252	GEDDES, "N-terminus truncated β -amyloid peptides and C-terminus truncated secreted forms of amyloid precursor protein: distinct roles in the pathogenesis of Alzheimer's disease," <u>Neurobiology of Aging</u> , 20:75-79 (1999).	
	253	GIULIAN, et al., "The HHQK Domain of b-Amyloid Provides a Structural Basis for the Immunopathology of Alzheimer's Disease," <u>Journal of Biological Chem.</u> , 273:29719-29726 (1998).	
	303	GONZALES-FERNANDEZ et al., "Low antigen dose favors selection of somatic mutants with hallmarks of antibody affinity maturation," <u>Immunology</u> , 93:149-153 (1998).	
	237	GORTNER, <u>Outlines of Biochemistry</u> , pp. 322-323, John Wiley & Sons, Inc., New York (1949).	
	254	GRUBECK-LOEBENSTEIN, et al., "Immunization with β -amyloid: could T-cell activation have a harmful effect?," <u>TINS</u> , 23:114 (2000).	
241	HAASS et al. "Amyloid beta-peptide is produced by cultured cells during normal metabolism," <u>Nature</u> , 359(6393):322-5 (1992).		

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Sheet 4 of 6

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Application Number	09/723,713
Filing Date	November 27, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1647
Examiner Name	Turner, Sharon
Attorney Docket Number	15270J-004741US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JD	255	HARIGAYA, et al., "Modified amyloid β protein ending at 42 or 40 with different solubility accumulates in the brain of Alzheimer's disease," <u>Biochem. Biophys. Res. Comm.</u> , 211:1015-1022 (1995).	/
	229	HAZAMA, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by Using a Recombinant Glycoprotein D Fused With Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2", <u>Immunology</u> , Vol. 78: 643-649 (1993).	/
	236	HILBICH et al., "Human and rodent sequence analogs of Alzheimer's amyloid β A4 share similar properties and can be solubilized in buffers of pH 7.4," <u>Eur. J. Biochem.</u> , 201:61-69 (1991).	/
	256	IKEDA, et al., "Immunogold labeling of cerebrovascular and neuritic plaque amyloid fibrils in Alzheimer's disease with an anti- β protein monoclonal antibody," <u>Lab. Invest.</u> , 57:446-449 (1987).	/
	257	JEN, et al., "Preparation and purification of antisera against different regions or isoforms of b-amyloid precursor protein," <u>Brain Research Protocols</u> , 2:23-30 (1997).	/
	258	KIDA, et al., "Early amyloid- β deposits show different immunoreactivity to the amino- and carboxy-terminal regions of b-peptide in Alzheimer's disease and Down's syndrome brain," <u>Neuroscience Letters</u> , 193:105-108 (1995).	/
	259	LANSBURY, PETER T., "Inhibition of amyloid formation: a strategy to delay the onset of Alzheimer's disease," <u>Curr. Ops. in Chemical Biology</u> , 1:260-267 (1997).	/
	260	LEMERE, et al., "Nasal A β treatment induces anti-A β antibody production and decreases cerebral amyloid burden in PD-APP mice," <u>Annals of the NY Acad. Sci.</u> , 920:328-331 (2000).	/
	261	MAK, et al., "Polyclonals to b-amyloid (1-42) identify most plaque and vascular deposits in Alzheimer cortex, but not striatum," <u>Brain Research</u> , 667:138-142 (1994).	/
	263	MANN, et al., "Amyloid β protein (A β) deposition in chromosome 14-linked Alzheimer's disease: Predominance of A β ₄₂₍₄₃₎ ," <u>Annals of Neurology</u> , 40:149-156 (1996).	/
	262	MANN, et al., "The extent of amyloid deposition in brain in patients with Down's syndrome does not depend upon the apolipoprotein E genotype," <u>Neuroscience Letters</u> , 196:105-108 (1995).	/
	264	McGeer, et al., "Immunohistochemical localization of beta-amyloid precursor protein sequences in Alzheimer and normal brain tissue by light and electron microscopy," <u>J. of Neuroscience Res.</u> , 31:428-442 (1992).	/
	238	MCNEAL et al., "Stimulation of local immunity and protection in mice by intramuscular immunization with triple- or double-layered rotavirus particles and QS-21," <u>Virology</u> , 243:158-166 (1998).	/
	265	Mena, et al., "Monitoring pathological assembly of tau and β -amyloid proteins in Alzheimer's disease," <u>Acta Neuropathol.</u> , 89:50-56 (1995).	/
JD	233	MORRIS, et al., "The Consortium to Establish a registry for Alzheimer's Disease (CERAD)," <u>Neurology</u> , 39:1159-65 (1989).	/

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26	250	NAKAMURA et al., "Histopathological studies on senile plaques and cerebral amyloid angiopathy in aged cynomolgus monkeys," <u>Exp. Anim.</u> , 43:711-718 (1995).	✓
	268	NAKAMURA, et al., "Carboxyl end-specific monoclonal antibodies to amyloid β protein (A β) subtypes (A β 40 and A β 42(43)) differentiate Ab in senile plaques and amyloid angiopathy in brains of aged cynomolgus monkeys," <u>Neuroscience Letters</u> , 201:151-154 (1995).	✓
	281	NAKAYAMA et al., "Histopathological studies of senile plaques and cerebral amyloidosis in cynomolgus monkeys," <u>J. of Med. Primatology</u> , 27:244-252 (1998).	✓
	235	NEWCOMBE and COHEN, "Solubility characteristics of isolated amyloid fibrils," <u>Biochim. Biophys. Acta</u> , 104:480-486 (1965).	✓
	280	PARDRIDGE et al., "Chimeric peptides as a vehicle for peptide pharmaceutical delivery through the blood-brain barrier," <u>Biochem. Biophys. Res. Comm.</u> , 146:307-313 (1987).	✓
	232	PETERSON, et al., "Recombinant Antibodies: Alternative Strategies for Developing and Manipulating Murine-Derived Monoclonal Antibodies," <u>Laboratory Animal Science</u> , 46(1):8-14 (1996).	✓
	269	PHILIPPE, et al. "Generation of a monoclonal antibody to the carboxy-terminal domain of tau by immunization with the amino-terminal domain of the amyloid precursor protein," <u>J. of Neuroscience Res.</u> , 46:709-719 (1996).	✓
	279	SAITO et al., "Vector-mediated delivery of ¹²⁵ I-labeled β -amyloid peptide Ab ¹⁻⁴⁰ through the blood-brain barrier and binding to Alzheimer disease amyloid of the A β ¹⁻⁴⁰ vector complex," <u>PNAS USA</u> , 92:10227-10231 (1995).	✓
	278	SAITOH, N. and K. IMAI, "Immunological analysis of Alzheimer's disease using anti- β -protein monoclonal antibodies," <u>Sapporo Med. J.</u> , 60:309-320 (1991).	✓
	277	SASAKI et al., "Human choroid plexus is an uniquely involved area of the brain in amyloidosis: a histochemical, immunohistochemical and ultrastructural study," <u>Brain Res.</u> , 755:193-201 (1997).	✓
	270	SCHENK, et al., " β -peptide immunization," <u>Arch. Neurol.</u> , 57:934-936 (2000).	✓
	271	ST. GEORGE-HYSLOP, PETER H. and DAVID A. WESTAWAY, "Antibody clears senile plaques," <u>Nature</u> , 40:116-117 (1999).	✓
	272	SZENDREI, et al., "The effects of aspartic acid-bond isomerization on <i>in vitro</i> properties of the amyloid β -peptide as modeled with N-terminal decapeptide fragments," <u>Int. J. Peptide Protein Res.</u> , 47:289-296 (1996).	✓
	273	THORSETT, E.D. and L.H. LATIMER, "Therapeutic approaches to Alzheimer's disease," <u>Curr. Op. in Chem. Biology</u> , 4:377-382 (2000).	✓
26	276	TJERNBERG et al., "Arrest of β -amyloid fibril formation by a pentapeptide ligand," <u>Journal of Biological Chemistry</u> , 271:8545-8548 (1996).	✓

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SO	274	WEINER et al., "Nasal administration of amyloid- β peptide decreases cerebral amyloid burden in a mouse model of Alzheimer's disease," <u>Annals of Neurology</u> , 48:567-579 (2000).	
	223	Wisconsin Alumni Research Foundation, "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals", U.S. Govt. Res. Develop. Rep. 70(24)-56- (Publication date unknown.) <i>Improper format</i>	
SO	275	WU, et al., "Drug targeting of a peptide radiopharmaceutical through the primate blood-brain barrier in vivo with a monoclonal antibody to the human insulin receptor," <u>J. Clin. Invest.</u> , 100:1804-1812 (1997).	
I	292	YAMAGUCHI et al., Diffuse plaques associated with astroglial amyloid β protein, possibly showing a disappearing stage of senile plaques," <u>Acta Neuropathol.</u> , 95:217-222 (1998).	
SO	290	YOUNKIN, "Amyloid β vaccination: reduced plaques and improved cognition," <u>Nature Medicine</u> , 7:18-19 (2001).	

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